PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION
(PCT Rule 66)

To:

GEARY, William C. III
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*	28.07.2004
REPLY DUE	**within 3 month(s)** from the above date of mailing

Applicant's or agent's file reference
022727-0101 WCG/REM

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 03/33316	21.10.2003	21.10.2002

International Patent Classification (IPC) or both national classification and IPC
G01R33/28

Applicant
THE GENERAL HOSPITAL CORPORATION D/B/A...et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 21.02.2005

Name and mailing address of the International preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer
Streif, J

Formalities officer (incl. extension of time limits)
Vilz, B
Telephone No. +49 89 2399-2292

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-32 as originally filed

Claims, Numbers

1-51 as originally filed

Drawings, Sheets

1/24-24/24 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 39,44,48-51

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 39,44,48-51

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-38,40-43,45-47 .

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Claims 1-10,12-17,19-25,27-31,36-38

Inventive step (IS)	Claims	11,26,32-35,40-43,45
Industrial applicability (IA)	Claims	42-45

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1 The following documents are referred to in this written opinion, the numbering will be adhered to in the rest of the procedure.

D1: Hurst GC et al, Magn. Reson. Med. 24, 343-357 (1992)
D2: Zimmermann GG et al, In: Debatin JF, Adam G, Interventional Magnetic Resonance Imaging, pages 283-293, Springer (1998)
D3: US5196796
D4: EP0850595
D5: EP1293793
D6: US5602557
D7: Nakada T et al, Magn. Reson. Med. 5, 449-455 (1987)
D8: US6326787
D9: US5572132
D10: JP5049614

Re item IV

2 Lack of unity (Rule 13 PCT)

The present application contains a number of separate inventions which do not share any common inventive concept, contrary to the requirements of Rule 13 PCT.

The common concept linking together these inventions is a coil which may comprise a meanderline conductive structure. However, this concept is not novel, see e.g. D1. Therefore, the defined subject-matter falls apart into a number of separate inventions that do not share any common or corresponding special technical features.

More specifically, claims 1-11, 19-38, 40-43 and 45 define a coil which may comprise a meanderline conductive structure, a medical catheter and a method suitable for magnetic resonance imaging and spectroscopy. It is considered that these claims do not define any special technical features with respect to D1.

Moreover, claims 12-18 define a coil assembly suitable for RF quadrature operation comprising a pair of conductive coils, where the feature defining that said coils are disposed in proximity of one another such that application of two

voltage signals having substantially equal amplitudes and about 90 degrees phase difference, each across one of said coils, generates a circularly polarized RF magnetic field can be considered as special technical feature with respect to D1.

Furthermore, claim 39 defines a feedback circuit suitable for monitoring and optimizing tuning of the coil that can be considered as special technical feature with respect to D1.

Moreover, claim 44 defines a method suitable for magnetic resonance imaging and spectroscopy wherein selected nuclei are polarized by a static magnetic field and the feature defining that said nuclei are any of phosphorus, carbon, oxygen or sodium can be considered as special technical feature with respect to D1.

Furthermore, claims 46 and 47 define a medical catheter where the tubular conductive structure is considered as special technical feature with respect to D1.

Finally, claims 48-51 define a medical catheter with two operational modes, wherein the feature defining that at least one elongated conductor extending along at least a portion of the flexible body of the catheter, said conductor being adapted for generating and/or receiving magnetic signals can be considered as special technical feature with respect to D1.

As a consequence, considering that the different inventions as listed above do not have any (corresponding) special technical features in common and that the underlying technical problems do not form a linear linked series of problems in that one solution was specifically adapted to another solution, there is a lack of unity within the meaning of Rule 13 PCT, and the claims actually define six groups of inventions.

Re item V

3 Lack of novelty and/or an inventive step (Articles 33(2) and 33(3) PCT)

3.1 Claims 1, 12, 21, 27, 42

Claim 1

The subject-matter of claim 1 would appear to lack novelty with respect to each of the documents D1-D6 and D9 for the following reasons.

For instance, document D1 discloses (references in parentheses referring to D1):

A coil suitable for transmitting and/or receiving magnetic excitations (see abstract), comprising:

- a meanderline conductive structure comprising a plurality of conductive segments (see the conductor paths of the four-wire multipole coil in figure 2e; it is noted that the left figure in figure 2e appears to show incorrect current directions; however, figure 34.1e of D2 clearly shows the meanderline conductive structure of the same four-wire multipole coil),

- forming a substantially cylindrical profile (see page 344, last paragraph and figure 2e; it is noted that D1 discloses also a six-wire version of the multipole coil with conductors symmetrically arranged about the cylinder; see the caption of figure 2),

- and generating a non-vanishing magnetic field distribution in response to current flow through said coil in a substantially annular region surrounding said conductive segments and a substantially vanishing magnetic field distribution in a region outside said annular region (see the phantom MR image of the four-wire mulipole coil depicted in figure 6 that corresponds to the distribution of the B_1 field).

In a similar way, the lack of novelty can be shown with respect to D2-D6 and D9 (see e.g. the passages cited in the search report; it is noted that the term "meanderline" is interpreted as a line that follows a winding course; therefore, the conductive structures disclosed in documents D2-D6 and D9 can be considered to

represent meanderline conductive structures).

Claim 12

The subject-matter of claim 12 would appear to lack novelty with respect to each of the documents D3, D6, D9 and D10 for the following reasons.

For instance, document D6 discloses (references in parentheses referring to D6):

A coil assembly suitable for radiofrequency quadrature operation, comprising a pair of conductive coils (the coils 4 and 6 in figure 1), each comprising

- an input terminal, an output terminal (each of the terminals 28 and 30 in figure 1), and

- a plurality of conductive segments extending from said input terminal to said output terminal (the loops of each of the coils 4 and 6 in figure 1),

- each of said conductive segments comprising two elongated conductors disposed substantially parallel to one another such that a flow of current from said input terminal to said output terminal results in opposite current directions in said conductors (the vertical conductors of each of the coils 4 and 6 in figure 1),

- wherein said conductive coils are disposed in proximity of one another (see figure 1) such that application of two voltage signals having substantially equal amplitudes and about 90 degree phase difference, each across one of said coils, generates a circularly polarized RF magnetic field (implicitly disclosed by referring to "circularly polarized operation", see col. 3, lines 10-11).

In a similar way, the lack of novelty can be shown with respect to D3, D9 and D10 (see e.g. the passages cited in the search report).

Claim 21

The subject-matter of claim 21 would appear to lack novelty with respect to each of the documents D1-D10 for the following reasons.

For instance, document D1 discloses (references in parentheses referring to D1):

A coil suitable for transmitting and/or receiving magnetic excitations (see abstract), comprising:

- a meanderline conductive structure comprising a plurality of conductive segments (see the conductor paths of the four-wire multipole coil in figure 2e; it is noted that the left figure in figure 2e appears to show incorrect current directions; however, figure 34.1e of D2 clearly shows the meanderline conductive structure of the same four-wire multipole coil),

- collectively forming a selected profile (the profile of a circular cylinder, see page 344, last paragraph and figure 2e),

- each conductive segment comprising at least two elongated conductors disposed substantially parallel to one another (see the conductor paths in figure 2e),

- said conductive structure further comprising an input terminal and an output terminal such that a flow of current from said input terminal to said output terminal will result in opposite current directions in said two elongated conductors of each of said conductive segments (see the current orientation in the right drawing of figure 2e).

In a similar way, the lack of novelty can be shown with respect to D2-D10 (see e.g. the passages cited in the search report).

Claim 27

The subject-matter of claim 27 would appear to lack novelty with respect to document D1 for the following reasons.

Document D1 discloses (references in parentheses referring to D1):

A medical catheter (see figure 4), comprising

- a flexible body extending from a proximal end to a distal end (the coaxial cable in figure 3b),

- a coil coupled to said flexible body in proximity of said distal end suitable for generating and detecting magnetic signals (the detector coil in figure 3b, although figure 3b depicts an opposed solenoid coil, it is stated on page 345, 2nd paragraph, that a multipole coil was studied as well), and

- an amplifier coupled to said catheter in proximity of said coil and electrically connected thereto in order to amplify said magnetic signals (see the FET in figure 3b).

Claim 42

a) The subject-matter of claim 42 would appear to lack an inventive step with respect to each of the documents D1 and D2 for the following reasons.

For instance, document D1 discloses (references in parentheses referring to D1):

A method suitable for magnetic resonance imaging and spectroscopy of at least a portion of a plaque on an interior wall of an artery (each of the spin echo and field echo pulse sequences is suitable for this purpose, see page 349, section "Imaging sequences"), comprising

- disposing a coil having a substantially cylindrical profile formed of a plurality of conductive segments in the artery in proximity of said plaque (although it is not clearly stated in D1 which particular coil is used in the in vivo experiments, it appears that these experiments were performed using the opposed solenoid coil, see figure 5 and section "In vivo canine images" on page 354), said conductive segments being configured such that a current flow through said coil generates a substantially vanishing magnetic field within a region within said cylindrical profile through which blood flows and a non-vanishing

magnetic field in an annular region in proximity of said conductive segments extending into at least a portion of said plaque (see the field characteristics of the opposed solenoid coil depicted in figure 6),

- applying a static magnetic field to said plaque to polarize selected atomic nuclei of constituents thereof (implicitly disclosed by referring to spin echo imaging and field echo imaging, see page 349, section "Imaging sequences"),

- applying a time-varying magnetic field in order to excite in said polarized nuclei (implicitly disclosed by referring to spin echo imaging and field echo imaging, see page 349, section "Imaging sequences"),

- utilizing said coil to detect radiation emitted by said excited nuclei (implicitly disclosed by referring to spin echo imaging and field echo imaging, see page 349, section "Imaging sequences").

The subject-matter of claim 42 would appear to differ from that of D1 only in that the catheter is inserted in a patient's artery rather than in a canine artery as in D1. However, it is considered that the application of the claimed method on animals represents an intermediate step in the development of an analogous method to be applied on patients. Furthermore, no further technical teaching is required in order to perform the method disclosed in D1 on patients rather than other mammals such as canines. Therefore, it appears that the skilled person would analogously use the method disclosed in each of the documents D1 and D2 on patients without the exercise of any inventive skill.

Even if the subject-matter of claim 42 would be amended such as to specify that the meanderline coil defined in claim 1 is used to perform the method, this would not appear to render the subject-matter of claim 42 inventive over each of the documents D1 and D2 since it is generally known to the skilled person that the various coil configurations disclosed in D1 and D2 are equivalent and can be interchanged where circumstances make it desirable.

b) Claim 42 relates to subject-matter considered by this Authority to be covered

by the provisions of Rule 67.1(iv) PCT. This claim defines a method comprising disposing a coil in a patient's artery. It is noted that this method step is considered to represent a method of treatment of the human body by surgery. Furthermore, the presence of a surgical step in a multi-step method confers a surgical character on that method.

Even if the definition was limited to a method of MR imaging via a coil already disposed within an artery, the method would imply the insertion in the subject (= catheterization). The step of catheterization qualifies as a method for treatment of the body by surgery.

Concerning the question whether the subject-matter of claim 42 is industrially applicable, no unified criteria exist in the PCT Contracting States. The EPO, for example, does not regard such methods to be susceptible of industrial application.

The same objection holds for the corresponding dependent claims 43-45.

3.2 Claims 2-11, 14-17, 19, 20, 22-26, 28-38, 40, 41, 43, 45

Claims 2-10, 20

The additional features of claims 2-10 and 20 are known, for instance, from document D1 (see figures 2e, 3a, 6 and section "Materials and fabrication process"; w.r.t. claim 3 see the current orientation in the right drawing of figure 2e; w.r.t. claims 9 and 20, see section "Tuning, coupling, cabling" on page 346).

Claim 11

By virtue of the clarity objection below, the embodiment depicted in figure 7 is used to compare the claimed subject-matter with the prior art. It is noted that D1 discloses a catheter configuration which allows continuous service of blood supply through the probe (see page 356, 2nd paragraph).

Therefore, the subject-matter of claim 11 differs from that of D1 in that the coil further comprises a substantially cylindrical conductive shield that restricts the RF magnetic field of the coil to the sample volume outside the coil. However, the

underlying technical problem and the use of an RF shield made of a conductive material (e.g. copper foil) to solve the problem are well-known in the art.

Since it is well-known that the sample volume is located outside the RF coil in intravascular applications, it appears that the skilled person, desiring to restrict the RF magnetic field of the coil disclosed in D1 to the sample volume, would screen the inner surface of the coil with a conductive shield, preferably extending coaxially along the full length of the coil. As a consequence, it is considered that the skilled person would arrive at the subject-matter of claim 11 without the exercise of any inventive skill.

Claims 13, 14

The additional features of claim 13 and 14 are known, for instance, from document D10 (see the two orthogonal butterfly coils depicted in the figure).

Claim 15

The additional feature of claim 15 is known, for instance, from document D9 (the conductor pattern depicted in figure 7a is wriggled on a cylindrical surface, see col. 8, 2nd paragraph).

Claims 16, 17

The additional features of claims 16 and 17 are known, for instance, from document D6 (see figure 1).

Claim 19

Claim 19 does not appear to define new features compared to a combination of claims 1-3. Therefore, the subject-matter of claim 19 is known, for instance, from document D1 as well.

Claims 22-24

The additional features of claims 22-24 are known from D1 as well (see figure 2a and 2e).

Claims 25, 26

The additional feature of claim 25 is known, for instance, from D1 as well (see section "Materials and fabrication process" on page 346, it is considered that the 28- to 36-gauge copper wire is "substantially rigid"). Furthermore, it appears that the additional feature of claim 26 defining that the conductive structure is substantially flexible represents an obvious design option to the skilled person.

Claims 28-31

The additional features of claims 28-31 are known from D1 as well (see figures 2e, 3, 6; section "Tuning, coupling, and cabling" on page 346-347; w.r.t. claim 29 it is considered that the catheter disclosed in D1 is biocompatible since it has been used for in vivo experiments).

Claim 32

The subject-matter of claim 32 differs from that of D1 in that said coil comprises an inductor electrically coupled to said capacitor and said coil for facilitating tuning said coil to said selected frequency. However, the advantages of inductors in matching networks of RF coils under particular load conditions are well-known in the art. Therefore, it is considered that the skilled person, desiring to improve matching of the coil impedance to the system impedance, would add an inductor to the matching network of the coil disclosed in D1 and arrive at the subject-matter of claim 32 without the exercise of any inventive skill (further documents will be cited if necessary).

Claims 33-38

The additional features of claims 33-38 are known, for instance, from D1 as well (see figures 2e, 3, 6 and sections "Materials and fabrication process" on page 346 and "Tuning, coupling, and cabling" on page 346-347; w.r.t. claims 34 and 35 it is noted that these features are considered to be implicitly disclosed by referring to NMR; w.r.t. claim 36 it is considered that the FET depicted in figure 3 represents a "low noise transistor"; w.r.t. claim 38 see page 346, lines 10-12 stating that "remote tuning ... was abandoned due to the inability to adequately isolate FET

power from varactor tuning voltage with a small number of components"; however, this is considered to implicitly disclose the use of varactor diodes for tuning of the coil, albeit with a higher "number of components").

Claims 40, 41

Claims 40 and 41 specify minor geometrical details that do not appear to add any technical effect to solve the problem posed. Unfortunately, it remains unclear from D1 if these features are present therein. However, it is considered that these features represent merely obvious design possibilities among the skilled person would select solely in accordance with circumstances, without the exercise of any inventive skill.

Claims 43, 45

The additional features of claims 43 and 45 are known, for instance, from D1 as well (w.r.t claim 43 see figure 11, it is implicitly clear that these images are proton images; w.r.t claim 45 it is noted that this feature is considered to be implicitly disclosed by referring to NMR).

4 Bearing in mind the objections under Article 6 PCT, it appears that the subject-matter of claims 18, 46, 47 is not disclosed in, nor rendered obvious from the available prior art.

Re item VIII

5 Lack of clarity, conciseness and support by the description (Article 6 PCT)

5.1 The various definitions of the invention in six independent apparatus claims are such that the set of claims as a whole is not concise. The claims should be recast to include only one independent claim per category with dependent claims that cover features that are merely optional.

5.2 Claims 1, 12, 19, 21

a) It should be clearly stated that the defined subject-matter relates to the technical field of NMR.

b) Concerning claim 1, the broad scope of the term "meanderline" including meanders with arbitrary shapes appears not to be supported by the description. The description merely supports a meanderline conductive structure where respective conductor paths are aligned in **parallel**.

c) Concerning claims 1 and 19, it appears that the features "generating a non-vanishing magnetic field distribution ... in a substantially annular region ... and a substantially vanishing magnetic field distribution in a region outside said annular region" define subject-matter in terms of the result to be achieved. The kind of conductors and their arrangement should be defined to make clear how this result is achieved. The same objection holds for claims 28, 42 and 47 as well.

d) It is unclear how a "conductive segment" is defined. Furthermore, the term "a plurality of conductive segments" appears to be misleading since the whole meanderline conductive structure forms **one contiguous** "conductive segment".

e) Concerning claim 19, although drafted as an independent claim, claim 19 contains all features of claim 1 and is therefore considered as a hidden dependent claim. Therefore, a reference to claim 1 should be added at the beginning of claim 19.

f) Concerning claims 1 and 19, the term "**substantially cylindrical**" is unclear and should be clarified, for instance by replacing it by the expression "cylindrical" used in the same context on page 14, line 6 of the description.

5.3 Claim 3

It should be clearly stated that the "elongated conductors" are aligned in parallel.

5.4 Claims 6, 7

a) Claims 6 and 7 appear to define subject-matter in terms of achieved results. It is not clear which further technical features are to be defined by the claims.

b) Concerning claim 6, the term "width" of the annular region is unclear and should be defined.

5.5 Claim 11

The broad scope of claim 11 appears not to be supported by the description and drawings. The description and drawings merely support a coil configuration which allows **blood flow through the coil** and a **cylindrical**, conductive shield disposed coaxially **inside** said coil (see e.g. figure 7).

5.6 Claim 12

Claim 12 would appear to cover arrangements not supported by the description (e.g. the orthogonal butterfly coils disclosed in D10). The description merely supports coil assemblies comprising a pair of meanderline coils, whereby the profile of both coils is **either cylindrical or flat**.

5.7 Claim 13

a) The term "corresponding conductive segment" should be clearly defined.

b) The unclear expression "substantially perpendicular" should be clarified, for instance by replacing it by the expression "perpendicular" used in the same context on page 19, line 1 of the description.

5.8 Claim 18

There appears to be a contradiction between claim 18 defining that "said coils are tuned to **different** frequencies" and claim 12 defining that said coils "generate a circularly polarized RF magnetic field", since the generation of a circularly polarized RF field requires that at least two coils are tuned to the **same** frequency.

5.9 Claim 21

a) The term "a selected profile" is unclear and should be defined.

b) The broad scope of the term "selected profile" appears not to be supported by the description. The description merely supports coils with flat or cylindrical profile.

5.10 Claims 23, 24

Claims 23 and 24 are obscure since these claims define subject-matter using properties of an external object ("patient's artery", "patient's anatomical surface") that does not form part of the claimed subject-matter.

5.11 Claims 25, 26

What is the difference between "substantially rigid" and "substantially flexible" ?

5.12 Claim 27

a) The broad scope of the term "a coil" appears not to be supported by the description. The description merely supports a medical catheter comprising a coil with a meanderline conductive structure.

b) The wording "catheter **comprising** ... an amplifier **coupled** to said catheter" is obscure since the wording "catheter comprising ... an amplifier" already implies that the amplifier is "coupled to said catheter".

5.13 Claim 30

The statement "said flexible body is sized to allow navigation of the catheter through a patient's artery" appears to define subject-matter in terms of the result to be achieved. Rather, it should be clearly defined how this effect is actually achieved.

5.14 Claim 34

The expression "in which the coil is inserted" is considered to be a method step rather than an apparatus feature and should therefore be replaced by the expression "in which the coil is **to be** inserted".

5.15 Claim 37

There appears to be a contradiction between claim 37 defining that "said amplifier is housed within said catheter" and claim 27 defining that the amplifier is "coupled to said catheter".

5.16 Claim 46

The broad scope of the term "a substantially tubular conductive structure" appears not to be supported by the description. The description merely supports a tubular

structure with a **contiguous** conductive surface. Furthermore, many different shapes are conceivable which are not supported by the description.

6 Further remarks

6.1 When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision of the application not to add subject-matter which extends beyond the content of the application as originally filed (Article 34(2)(b) PCT).

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

In carrying out the amendments, the applicant will most likely begin with the presently recorded text and make manuscript amendments before having the latter retyped. Such a manuscript amended copy would be invaluable to the examiner in his reviewing of the case. He would therefore be indebted to the applicant if such a copy would be included together with the type written copies in his letter of reply.

6.2 The independent claims have not been drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

6.3 According to Rule 6.2(b) PCT, reference signs in parentheses should be added to the claims to increase their intelligibility.

6.4 According to Rule 11.11 PCT, the drawings should not contain any text matter except a single word or words, when absolutely indispensable.

6.5 To meet the requirements of Rule 5.1a (ii) PCT, documents D1 and D2 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.